ABSORB China: Two-Year Clinical Results in Patients with Coronary Artery Disease Randomized to the Absorb Bioresorbable Vascular Scaffold Versus Metallic Drug-Eluting Stents

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On behalf of ABSORB China Investigators

Disclosures

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ABSORB China

Prospective, randomized, active control, open-label, multicenter study in 480 subjects enrolled from 24 sites in China

Inclusion: Up to 2 *de novo* lesions in separate native coronary arteries
Lesion length ≤24 mm, RVD ≥2.5 mm - ≤3.75 mm, %DS ≥50% - <100%

Exclusion: AMI, EF <30%, eGFR <30 mL/min/1.73m^2,
LMCA, ostial lesion, excessive vessel tortuosity, heavy calcification, myocardial bridge, bifurcation with side branch ≥2 mm

1: 1 Randomization

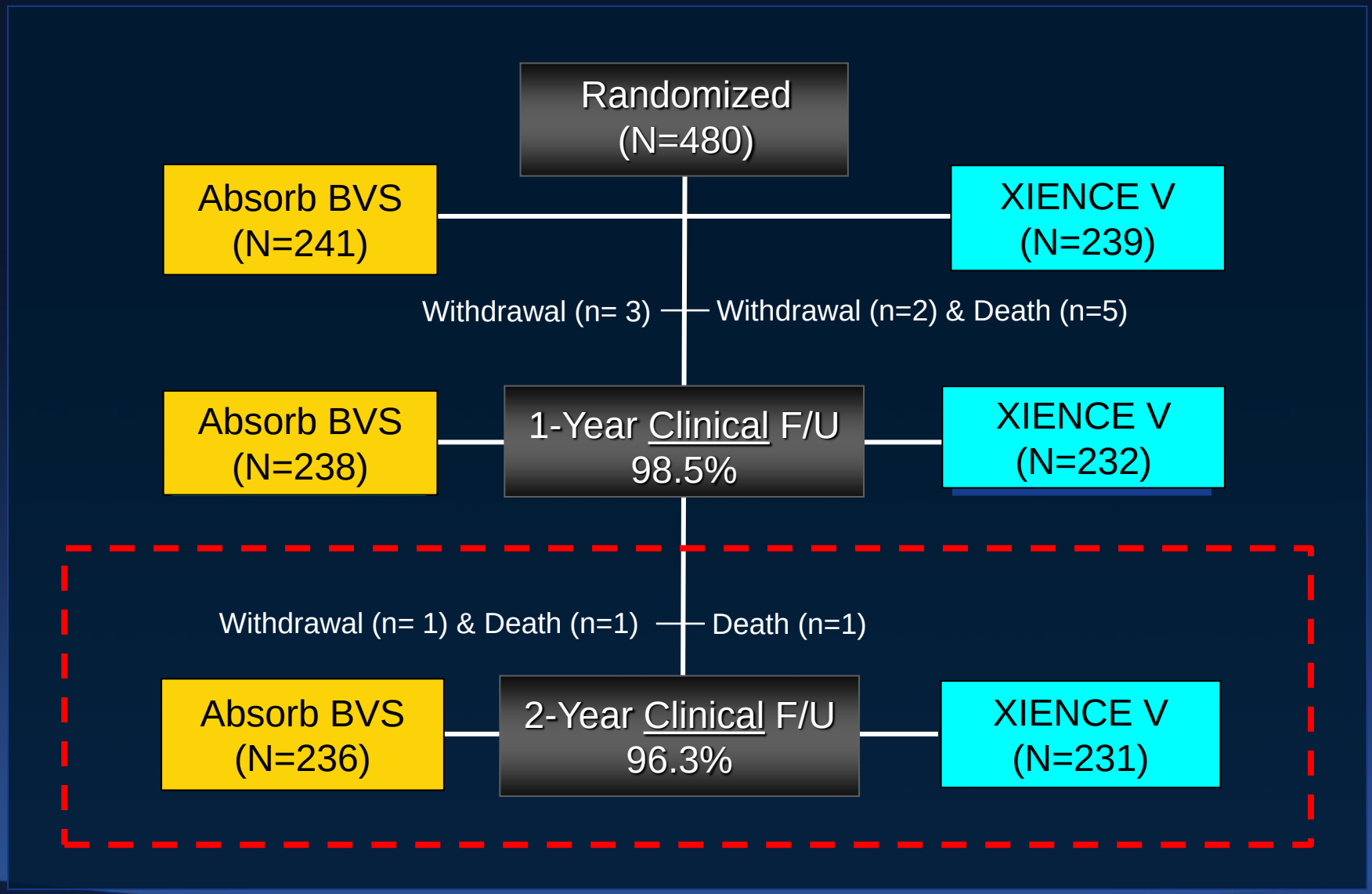
Absorb BVS
Treat with single study device
Diameters: 2.5, 3.0. 3.5 mm
Lengths: 8, 12, 18, 28 mm

XIENCE V
Treat with single study device
Diameters: 2.5, 3.0. 3.5 mm
Lengths: 8, 12, 18, 28 mm

Primary Endpoint: In-Segment Late Loss at 1 Year in the Per-Treatment-Evaluable (PTE) Population*

** Treated with only the study device (Absorb BVS or XIENCE V) and with no mixed devices at target lesion and no pre-specified major protocol deviations*

Patient Flow and Follow-up (ITT)



2-Year Clinical Composite Endpoints

	Absorb BVS (N=241)	XIENCE V (N=239)	P-Value
PoCE (DMR)	10.1% (24/237)	11.4% (27/237)	0.66
DoCE (TLF)	4.2% (10/237)	4.6% (11/237)	0.82
MACE	5.1% (12/237)	5.1% (12/237)	1.00
TVF	5.5% (13/237)	6.8% (16/237)	0.57

PoCE=patient-oriented composite endpoint (all-cause death, all MI, or any revascularization); DoCE=device-oriented composite endpoint (cardiac death, TV-MI*, or ID-TLR); * CK-MB > 5x ULN for peri-procedural PCI MI*

2-Year Clinical Component Endpoints

	Absorb BVS (N=241)	XIENCE V (N=239)	P-Value
All-cause death	0.4% (1/237)	2.5% (6/237)	0.12
- Cardiac death	0.4% (1/237)	1.3% (3/237)	0.62
All MI*	3.0% (7/237)	2.1% (5/237)	0.56
- TV-MI*	2.1% (5/237)	0.8% (2/237)	0.45
All revascularization	8.9% (21/237)	8.4% (20/237)	0.87
- ID-TLR	3.4% (8/237)	2.5% (6/237)	0.59

** CK-MB > 5x ULN for peri-procedural PCI MI*

Scaffold/Stent Thrombosis

	Absorb BVS (N=241)	XIENCE V (N=239)	P-Value
All (0 - 730 days)	0.8% (2/237)	0.0% (0/231)	0.50
Definite	0.4% (1/237)	0.0% (0/231)	1.00
Probable	0.4% (1/237)	0.0% (0/231)	1.00
Early (0 – 30 days)	0.4% (1/238)	0.0% (0/236)	1.00
Late (31- 365 days)	0.0% (0/238)	0.0% (0/232)	1.00
Very Late (366- 730 days)	0.4% (1/237)	0.0% (0/231)	1.00

There were 1 probable, subacute (1-30d) ST and 1 definite, very late ST in the Absorb BVS arm.

Summary and Conclusion

- Trial well conducted:
  - High clinical f/u rate: 1-year = 98.5%; 2-year = 96.3%
  - Independent CEC, angiographic core lab, and DSMB
  - 100% data monitoring conducted by the sponsor
  - Additionally, an independent, third-party data verification by the sites' GCP offices was performed as mandated by the new GCP regulations in China.
- The rates of clinical events, including TLF, cardiac death, TV-MI, ID-TLR, and device thrombosis were generally low and comparable between Absorb BVS and XIENCE V through 2 years.

Thank you